

# *The Perennial Challenge to Modern Clinical Investigation*

DEAN T. MASON, MD, *Davis, California*

AT THIS TIME during our annual meeting, it is expected that the president of this society should deliver a concise address of infinite wisdom taking into account all that is important in the pursuit of clinical investigation. Further, it is usually anticipated that—to be in tune with the contemporary interface between the academic world and society—the presidential address will focus on some issue of high significance relating public policy to clinical science. In considering the multiplicity of timely subjects which I might discuss, it struck me that the principal problems facing the performance of clinical investigation today are, perhaps in disguise, the same perplexities that have always been cause for concern to all of us who have devoted a major portion of our professional lives to medical research and education, and who wish to continue to do so in the future. What I have in mind is our concern for the proper balance between the three cardinal factors of ethics and resources and priorities on one hand, and scientific progress on the other. This I would term the perennial challenge to the clinical investigator. The important subject of ethics in clinical research has been well expounded upon by others;

my remarks will be directed more to the problems of resources and priorities in medical science.

While no serious doubt exists, even at this time, that the development of new knowledge through biomedical research is essential for advancing the health of the American people, there is growing apprehension in the academic community regarding the size and direction of support allotted for the conduct of research. A genuine anxiety exists among many investigators that we may be living on borrowed time. Numerous questions have been raised concerning the development and delivery of medical knowledge: How should priorities be set for research programs? What should be the appropriate relation between investigation and health service needs? What is the proper balance between basic and clinical research? To what extent should investigation be targeted, as opposed to investigator-initiated? What should be the degree of support for the development of research manpower? And what role does research play in the education of the health professions? At an extreme, there is a segment of society which advocates that the whole of our medical resources and energies be centered on correcting the unfilled health delivery needs of the nation and there are those who, because of inflationary costs, demand fiscal ischemia solely for economy's sake by curtailing government spending in activities of least political significance. To say the least, the climate for the stable long-range support of medical science and

Presidential Address, Twenty-Eighth Annual Meeting, Western Society for Clinical Research, Carmel, California, February 6, 1975.

The author is Professor of Medicine and Physiology; Chief, Section of Cardiovascular Medicine, Department of Internal Medicine, University of California, Davis, School of Medicine.

Reprint requests to: D. T. Mason, MD, Section of Cardiovascular Medicine, University of California, Davis, School of Medicine, Davis, CA 95616.

education as we have known it in the past will clearly not be a part of the future. The ready availability of federal health dollars which flowered the monumental medical advances in the 20-year golden era of biomedical research following the Second World War has now been history for a full decade.

The complex and uncertain position of the support of medical science today is, of course, principally the result of a national desire for adaptations in our health system with public debate in recent years focused on revision of the balance between health care necessities and the development of new knowledge, the need for greater physician and related health care manpower, the reorganization of the health care delivery mechanism itself, and a means for assuring high quality health care provided at a controlled cost. These fluctuations in national health priorities have led to recent federal legislation establishing regional Professional Standards Review Organizations (PSROs), local Health Maintenance Organizations (HMOs) emphasizing prevention of illness, the Emergency Medical Service Systems Act and the major new Health Manpower Bill currently before Congress. The Health Manpower Bill would provide for nearly half of the total budgets of this nation's medical schools in exchange for substantial governmental involvement in enlargement of student enrollment, geographic distribution of graduates toward health scarcity areas and curtailment of certain specialty training programs in favor of increased primary care residencies. Also, a principal assumption underlying the Department of Health, Education and Welfare's Forward Plan for Health is that a form of national health insurance will be fully operative within the next five years. This augmentation of health care delivery programs contains some features which should substantially improve the health of our citizens, and I think that most of us in academic medicine would view certain of these measures as being salutary developments. Of grave concern to us, however, has been the unfortunate side effects of this recasting of the health industry of dangerously lowering the priorities and resources for biomedical research and neglecting the support of health research traineeships.

It does not require emphasizing to this audience that our health care system will become desperately crippled if biomedical research is allowed to wither, and a proper balance must be regained between patient care and investigation. Obviously,

all of the health care that there is to deliver really represents the total evolution of medical knowledge resulting from critical analysis, both clinical and laboratory, through the ages. The number of clinical diseases that we can neither prevent nor cure is still enormous, and it is clear that no important inroads will be made without a return to a steady, purposeful expansion of basic and clinical research. Although there are claims to the contrary, in my opinion the gap is no longer between clinically useful knowledge and what is available to the public. Also, it should be pointed out to those who are obsessed with economics, research can play a vital role in improving the efficiency and diminishing the spiraling costs of the health care industry by developing improved therapy and preventive measures for presently unmanageable and incapacitating diseases. In addition, it is safe to say that medical teaching is best carried out in an atmosphere of scientific inquiry in order to translate the scholarly process of problem solving to patient care, so that the practice of medicine remains a learned profession rather than a skilled trade. The practical benefits of the education of physicians being based on a firm understanding of scientific principles are numerous. One example that comes immediately to my mind, relative to the discipline of cardiovascular medicine, is the recent clinical application of a new dimension in the treatment of refractory heart failure. This is the use of peripheral vasodilator agents for the relief of pulmonary congestion, elevation of cardiac output and reduction of myocardial ischemia. It became recognized as a rational, innovative therapeutic approach based entirely on an improved understanding of the physiologic factors regulating ventricular function.

How can we, the clinical academic community devoted to research into the course and treatment of human illness, make ourselves heard in a meaningful manner to effect a stable national policy regarding biomedical research? The Association of American Medical Colleges (AAMC) has emerged as a much needed and effective spokesman in Washington for medical research and education. Additional approaches are necessary, however, and they demand the best efforts of each of us. Probably our most important obligation is to improve our communication with the public who, after all, finance medical research. They have a right and need to know about our work, knowledge, problems and opportunities for progress as these relate to the betterment of society. We need

to make medicine less of a mystery and improve the art of talking about science with the press and news media.

I would like to conclude by bringing to your attention four recent undertakings in improving the state of scientific affairs in cardiovascular medicine. They were carried out by the professional subspecialty society with which I identify, and might well serve as useful endeavors for many of the other subspecialties within internal medicine—as well as the broad-based discipline of internal medicine itself. Concerning the first activity, the American College of Cardiology (ACC) recently completed a comprehensive National Institutes of Health (NIH) supported manpower study of cardiologists to define their current professional roles, to determine training objectives, to consider present and future manpower needs and to determine postgraduate educational requirements. Approximately 11,000 cardiologists were identified in active practice in the United States, resulting in a ratio of five such physicians per 100,000 population. Fifty percent are certified in internal medicine while only 10 percent have taken cardiovascular boards. Four general activity profiles of cardiologists were identified: noninstitutional internist-cardiologists, constituting a third of the total; noninstitutional clinical cardiologists, making up half of the manpower; institutional cardiac specialists, who largely constitute the remaining one sixth, and institutional academic cardiologists. On the basis of the high prevalence of cardiovascular disease, population growth and other factors, it was judged that approximately 5,000 additional cardiologists would be necessary by 1976 to obtain a needed six per 100,000 cardiologist-to-population ratio. In addition, this study defined the appropriate component needs of cardiology training programs and indicated the need for different types of programs to train different types of cardiologists.

Second, the ACC has established the Bethesda Conferences for exchange of ideas and formulation of policies by recognized authorities concerning matters of patient care, research and training in cardiovascular medicine. For example, the recent Conference on the Development and Introduction of New Cardiovascular Drugs brought together a large body of professionals in basic and clinical investigation, the pharmaceutical industry and regulatory government agencies to discuss problems concerning the timely and ethical development and clinical use of safe and effective

drugs. A number of difficulties were identified, for which the participants jointly developed solutions. It was recommended that a Standing Advisory Committee be established composed of members of the ACC and the American Heart Association to consider criteria for efficacy and related issues in clinical cardiovascular pharmacology and therapeutics with the purpose of providing liaison between academic investigators, the Food and Drug Administration, the pharmaceutical industry and the National Heart and Lung Institute.

Third, the American College of Cardiology has initiated the development of a unique facility for postgraduate learning: construction of a national center for continued education, called Heart House, located in Bethesda adjacent to the NIH campus. The purpose of Heart House is to serve as the principal resource headquarters for the advanced teaching of cardiovascular medicine in which both group and self instruction are provided for, to afford a site for exploration of new teaching methods and to aid cardiovascular education throughout the nation and the world by development and distribution of all types of educational materials. In regard to postgraduate instruction, the American College of Cardiology also conducts approximately 35 regional scientific programs in cardiology each year in the United States through the coordination of the College's Committee on Continuing Education. In addition, the Self-Evaluation in Cardiology examination has recently been developed by the College in cooperation with the American Heart Association.

Fourth, the American College of Cardiology has organized the International Educational Program on Cardiovascular Diseases in cooperation with the Bureau of Education and Cultural Affairs of the United States State Department. This program provides the means for exchange of knowledge between the visiting faculty and host countries and affords the medical community of all nations opportunities in continuing education. During the past decade, the ACC faculty has carried out 40 such circuit courses and taught in approximately 50 countries around the world. This visiting educational program has established lasting friendships among physicians, governments and people of many nations—and has united across national borders those concerned with the treatment of heart disease.

In summary, my purpose has been to delineate

what I consider to be a perpetually consistent theme in the planning and performance of clinical investigation: the appropriate relation between—on one hand—proper ethics, availability of resources and health priorities and—on the other—the need for scientific advancements. This relationship may shift dramatically according to the overall necessities, economy and politics of our society. Our society and its representatives must come to grips with whether it is really wise to redistribute the federal budget towards military expenditures and over-involvement in foreign economies at the expense of pressing domestic needs, such as in health by withholding support of the growth and even maintenance of the medical sciences. In times past, resources for clinical investigation were relatively easily obtainable. However, today they are not and so the fruition of clinical investigation requires, among other

attributes, considerable patience, much persistence and long hours of hard work, coupled with (perhaps the most important factor) an understanding spouse.

For optimal health care, it is axiomatic that medical research be reequilibrated with the health services. The waste of our most precious health resource is the loss of the research time of talented investigators with imaginative ideas that may ultimately lead to improvements in patient care, who are unable to carry out their work because of inadequate government planning for the support of the development of new knowledge. Perhaps I am somewhat of an optimist by nature, but I think that a growing body of congressional authorities are beginning to appreciate that augmentation of health research complements rather than competes with health care delivery. Nevertheless, we have a very long way to go.